STATUTORY INSTRUMENTS

2021 No. 1452

The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021

New regulation 167A (NIMAR supply to Northern Ireland) and new regulation 167B (list of NIMAR products)

14. After regulation 167(**1**) (supply to fulfil special patient needs), insert—

"**NIMAR supply to Northern Ireland**

167A.—(1) If the following conditions are met—

(a) the prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product sold or supplied, or offered for sale or supply, in Northern Ireland, and

(b) that product is classified in Northern Ireland as a prescription only medicine.

(2) Condition A is that a UK marketing authorisation of a following type is in force for the product—

(a) a UKMA(UK);

(b) a UKMA(GB).

(3) Condition B is that the product is classified as a prescription only medicine in accordance with regulation 5(3) for the purposes of sale and supply in Great Britain.

(4) Condition C is that the product is a listed NIMAR product.

(5) Condition D is that if the product is to be distributed by wholesale dealing by a person ("P") in Northern Ireland, P must be a holder of a wholesale dealer's licence.

(6) Condition E is that if the product is manufactured or assembled in Great Britain, it is supplied to Northern Ireland—

(a) by the holder of a manufacturer's licence in respect of that product; or

(b) by the holder of a wholesale dealer's licence.

(7) Condition F is that if the product is manufactured outside of the UK and imported into Great Britain, it is supplied to Northern Ireland—

(a) by a holder of a manufacturer's licence in respect of that product; or

(b) by the holder of a wholesale dealer's licence.

List of NIMAR products

167B.—(1) The licensing authority must maintain a list for the purposes of regulation 167A(4).

(**1**) Regulation 167, amended by S.I. 2017/715 and 2019/775 as amended by 2020/1488.

(2) In relation to each listed NIMAR product, the list must specify the date the NIMAR product was added to the list.

(3) The licensing authority must publish the list and keep it up to date.

(4) A product may only be included on the list if the following conditions are satisfied—

(a) Condition A is that the Secretary of State has in relation to Northern Ireland been provided with at least one of the following—

(i) information requested under regulation 28 (provision of information about availability of health service medicines) of the 2018 Regulations;

(ii) information under regulation 29 (requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines) of the 2018 Regulations;

(b) Condition B is that the holder of a UK marketing authorisation, has notified the Secretary of State that—

(i) in relation to a medicinal product to which a UKMA(UK) relates, the qualified person who is at the disposal of the holder of a manufacturer's licence is unable to secure the matters mentioned in paragraph 12A of Schedule 7 for the purpose of supplying the product into Northern Ireland from Great Britain; or

(ii) in relation to a medicinal product to which a UKMA(GB) relates, the inability of a qualified person who is at the disposal of the holder of a manufacturer's licence to secure the matters mentioned in paragraph 12A of Schedule 7 prevents the holder of the UKMA(GB) from converting it into a UKMA(UK);

(c) Condition C is that the licensing authority considers that clinical needs in Northern Ireland for the product may be unmet.

(5) The licensing authority must remove a product from the list if the licensing authority considers that medicinal products, not including listed NIMAR products, available in Northern Ireland are capable of meeting clinical need.".